



1636

I hereby certify that this correspondence is being deposited with the US Postal Service with sufficient postage as to permit Class Mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231, on the date shown below.

Date: April 15, 2003

By: Carol A. See  
Carol A. See

**PATENT**  
**Docket No. GC589-4**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of	)	
	)	
Manley Huang et al.	)	Group Art Unit: 1636
	)	
Serial No. 09/938,689	)	Examiner: Nguyen, Quang
	)	
Filed: August 23, 2001	)	
	)	
For: Transgenic Mammal Capable of	)	
Facilitating Production of Donor-	)	
Specific Functional Immunity	)	

**RECEIVED**  
APR 24 2003

**Information Disclosure Statement** **TECH CENTER 1600/2900**

Commissioner for Patents  
Washington, DC 20231

Sir:

Applicants submit herewith patents, publications or other information (listed on the attached Form PTO-1449 and attached thereto) of which they are aware, that they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement:

- (a) ☐ accompanies the new patent application submitted herewith. 37 CFR §1.97(a).
- (b) ☐ is filed within three months after the filing date of the application or within three months after the date of entry into the national stage of a PCT application as set forth in 37 CFR §1.491.
- (c) ☒ as far as is known to the undersigned, is filed before the mailing date of a first Office Action on the merits.
- (d) ☐ is filed after the first Office Action and more than three months after the application filing date or PCT national stage date of entry filing but, as far

as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and is accompanied by either the fee (\$180.00) set forth in 37 CFR §1.17(p) or a certification as specified in 37 CFR §1.97(e), as checked below. Authorization to charge Deposit Account No. 07-1048 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement is provided in the Transmittal Letter submitted herewith in duplicate.

(e) ☐ is filed after the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by authorization (in the Transmittal Letter submitted herewith in duplicate) to charge Deposit Account No. 07-1048 the fee (\$180.00) set forth in 37 CFR §1.17(l)(1) and a certification as specified in 37 CFR §1.97(e), as checked below. **This document is to be considered as a petition requesting consideration of the Supplemental Information Disclosure Statement.**

[If either of boxes (d) or (e) is checked above, the following "certification" under 37 CFR §1.97(e) may need to be completed.] The undersigned certifies that:

☐ Each item of information contained in the Information Disclosure Statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ No item of information contained in this Information Disclosure Statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

A copy of the items on Form PTO-1449 is supplied: PCT International Search Report for PCT/\_\_\_\_\_, filed \_\_\_\_\_ with attached patents and publications.

☐ each ☒ none ☐ only those listed below:

Those patent(s) or publication(s) which are marked with an asterisk (\*) on the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Office in a prior application, Serial No. 09/651,361, filed August 30, 2000, and relied upon in this application for an earlier filing date under 35 USC 120.

Also, those patent(s) or publication(s) which are marked two asterisks (\*\*) on the attached Form PTO-1449 (**Books not sent**) are not supplied. Complete bibliographic information is unknown

or unavailable. The cited publications are books or reference manuals and are commonly available. Reproduction of such publications would result in a voluminous submission.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☒ not given
- ☐ given for each listed item
- ☐ given for only non-English language listed item(s)
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

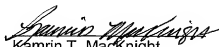
The Examiner is reminded that a "concise explanation of the relevance" of the submitted prior art "may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention." MPEP §609.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR §1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR §1.97(b), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR §1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR §1.98 and MPEP §609 and the Examiner is respectfully requested to consider the listed references.

Respectfully submitted,

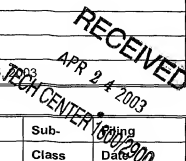
Date: 14 April 2003

  
Kamrin T. MacKnight  
Registration No. 38,230

Genencor International, Inc.  
925 Page Mill Road  
Palo Alto, CA 94304-1013  
Tel: 650 846-5838  
Fax: 650 845-6504

**INFORMATION DISCLOSURE CITATION**

<b>Attorney Docket No.:</b> GC589-4	<b>Serial No.:</b> 09/938,689
<b>Applicant:</b> Huang et al.	
<b>Filing Date:</b> August 23, 2001	<b>Group:</b> 1636
<b>Page</b> <u>1</u> <b>of</b> <u>6</u>	<b>Date of this Submission:</b> April 15, 2003



**US PATENT DOCUMENTS**

Examiner's Initial	Document Number	Date	Name	Class	Sub-Class	Sub-Class	Date
	*5,487,992	1/30/96	Capecchi et al.	435	172.3		6/28/93
	*5,434,340	7/18/95	Krimpenfort et al.	800	2		7/27/92
	*5,814,318	9/29/98	Lonberg et al.	424	184.1		7/22/93
	*5,859,307	1/12/99	Mombaerts et al.	800	2		6/7/94
	*4,873,191	10/10/89	Wagner et al.	435	172.3		8/18/86

**OTHER DOCUMENTS**

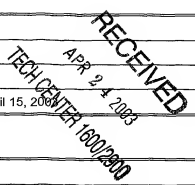
Examiner's Initials	Author, Title, Date, Pertinent Pages, etc.
	**Ausubel, F. et al., ed. Current Protocols in Molecular Biology, Greene Publishing and Wiley Interscience, New York, 1987.
	*Antoine, Jean-Claude et al., « H-2M molecules, like MHC class II molecules, are targeted to parasitophorous vacuoles of Leishmania-infected macrophages and internalized by amastigotes of L. amazonensis and L. mexicana, » Journal of Cell Science, vol. 112, pp. 2559-2570, 1999.
	*Bhatia, Mickie et al., « Purification of primitive human hematopoietic cells capable of repopulating immune-deficient mice, » Proc. Natl. Acad. Sci., U.S.A., vol. 94, pp. 5320-5325, May, 1997.
	*Bix, Mark et al., « Rejection of class I MHC-deficient haemopoietic cells by irradiated MHC-matched mice, » Nature, vol. 349, pp. 329-331, January 24, 1991.
	*Bix, Mark et al., « Inefficient positive selection of T cells directed by haematopoietic cells, » Nature, vol. 359, pp. 330-333, September 24, 1992.
	*Bonaventure, P. et al., « Humanization of Mouse 5-Hydroxytryptamine 1B Receptor Gene by Homologous Recombination : In Vitro and In Vivo Characterization, » Molecular Pharmacology, vol 56, pp. 54-67, 1999.
	*Bradley, Allan et al., « Modifying the Mouse : Design and Desire, » BioTechnology, vol. 10, pp. 534-539, May, 1992.
	*Brouard et al., "Transplantation of stromal cells transduced with the human IL3 gene to stimulate hematopoiesis in human fetal bone grants in non-obese, diabetic-severe combined immunodeficiency mice," Database Medline "Online" (Accession No: 1996326137) US Natl. Lib. Of Med. (1996) Leukemia, 12 (7) 1129-55 (XP-002157437) ABSTRACT
	*Bleich, M. et al., « Pflügers Arch-Eur. J. Physiol., vol. 438, pp. 245-254, 1999.
	*Bock, Thomas et al., « Improved Engraftment of Human Hematopoietic Cells in Severe Combined Immunodeficient (SCID) Mice Carrying Human Cytokine Transgenes, » Journal of Experimental Medicine, vol. 182, pp. 2037-2043, December, 1995.
	*Brinster, Ralph L. et al., « Factors affecting the efficiency of introducing foreign DNA into mice by microinjecting eggs, » Proc. Natl. Acad. U.S.A., vol. 82, pp. 4438-4442, July, 1985.

<b>Examiner</b>	<b>Date Considered</b>

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. PTO-1449

**INFORMATION DISCLOSURE CITATION**

<b>Attorney Docket No.:</b> GC589-4	<b>Serial No.:</b> 09/938,689
<b>Applicant:</b> Huang et al.	
<b>Filing Date:</b> August 23, 2001	<b>Group:</b> 1636
<b>Page</b> <u>2</u> <b>of</b> <u>6</u>	<b>Date of this Submission:</b> April 15, 2003



**OTHER DOCUMENTS**

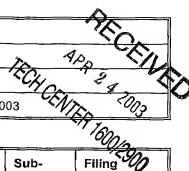
Examiner's	
Initials	Author, Title, Date, Pertinent Pages, etc.
	*Capecchi, Mario R., « Altering the Genome by Homologous Recombination, » Science, vol. 244, pp. 1288-1292, June 16, 1989.
	*Cashman et al., "Human growth factor-enhanced regeneration of transplantable human hematopoietic stem cells in nonobese diabetic/severe combined immunodeficient mice," <i>Database Medline 'Online! (Accession No. 1999102377) US Natl. Lib. Of Med. (1999) Blood 93 (2) 481-7 (XP-002157436) ABSTRACT</i>
	*Colas, G. et al., « The Xenotransplantation of Goat and Human Hematopoietic Cells to Sheep Fetuses, » Transplantation, vol. 67, no. 7, pp. 984-990, April 15, 1999.
	*Cuzzocrea, Salvatore et al., « Role of interleukin-6 in a non-septic shock model induced by zymosan, » European Cytokine Network, vol. 10, issue 2, pp.191, June, 1999.
	*Dao et al., "Immunodeficient mice as models of human hematopoietic stem cell engraftment," <i>Current Opinion in Immunology (1999) 11 (5) 532-7, ref. 49, pg. 533, col. 2, line 3-14 (XP-000972857)</i>
	*Dao et al., "Long-term cytokine production from engineered primary human stromal cells influences human hematopoiesis in an in vivo xenograft model," <i>Database Medline 'Online! (Accession No. 1998066277) US Natl. Lib. Of Med. (1997) Stem Cells 15 (6) 443-54 (XP-002157438)</i>
	*Dick, John E. et al., « Assay of Human Stem Cells by Repopulation of NOD/SCID Mice, » Stem Cells, vol. 15, suppl. 1, pp. 199-203, 1997.
	*Evans, M.J. et al., « Establishment in culture of pluripotential cells from mouse embryos, » Nature, vol. 292, July 9, 1981.
	*Gossler, Achim et al., « Transgenesis by means of blastocyst-derived embryonic stem cell lines, »Proc. Natl. Acad. Sci., USA, vol. 83, pp. 9065-9069, December, 1986.
	*Gubler, Ueli et al., « A simple and very efficient method for generating cDNA libraries, » Gene, vol. 25, pp. 263-269, 1983.
	*Haber, James E., « DNA recombination : the replication connection, » Trends, Biochem. Sci., vol. 24, pp. 271-275, July, 1999.
	*Harkki, A et al., « A Novel Fungal Expression System : Secretion of Active Calf Chymosin from the Filamentous Fungus Trichoderma Reeseli, » Bio/Technology, vol. 7, pp. 596-603, June, 1989.
	*Hauser, Wolfgang et al., « Megakaryocyte hyperplasia and enhanced agonist-induced platelet activation in vasodilator-stimulated phosphoprotein, »Proc. Natl. Acad. Sci. USA, vol. 96, pp. 8120-8125, July, 1999.
	**Hogan, Christopher J. et al., « Manipulating the Mouse Embryo, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, 1986.
	*Hogan, Christopher J. et al., « Multilineage engraftment in HOD/LtSz-scid/scid mice from mobilized human CD34+ peripheral blood progenitor cells, » Biology of Blood and Marrow Transplantation, vol. 3, pp. 236-246, 1997.
	*Hogan, Christopher J. et al., « Engraftment and Development of Human CD34+-Enriched Cells from Umbilical Cord Blood in NOD/LtSz-scid/scid Mice, Blood, vol. 90, no. 1, pp. 85-96, July 1, 1997.

<b>Examiner</b>	<b>Date Considered</b>

**Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **PTO-1449**

## INFORMATION DISCLOSURE CITATION

Attorney Docket No.: GC589-4	Serial No.: 09/938,689
Applicant: Huang et al.	
Filing Dat : August 23, 2001	Group: 1636
Page <u>3</u> of <u>6</u>	Date of this Submission: April 15, 2003



## US PATENT DOCUMENTS

Examiner's	Document				Sub-	Filing
Initial	Number	Date	Name	Class	Class	Dat

## FOREIGN PATENT DOCUMENTS

Examiner's	Document				Sub-	Translation
Initials	Number	Date	Country	Class	Class	Yes/No

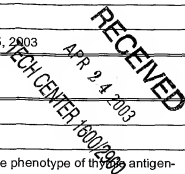
## OTHER DOCUMENTS

Examiner's	
Initials	Author, Title, Date, Pertinent Pages, etc.
	*Hugo, Patrice et al., « Fibroblasts can induce thymocyte positive selection in vivo, « Proc. Natl. Acad. Sci., USA, vol. 90, pp. 10335-10339, November, 1993.
	*Jaenisch, Rudolf, « Germ line integration and Mendelian transmission of the exogenous Moloney leukemia virus, » Proc. Natl. Acad. Sci. USA, vol. 73, no. 4, pp. 1260-1264, April, 1976.
	*Jaenisch, Rudolf, « Transgenic Animals, » Science, vol. 240, pp. 1468-1474, 1988.
	*Jahner, Detlev et al., « Insertion of the bacterial gpt gene into the germ line of mice by retroviral infection, » Proc. Natl. Acad. Sci. USA, vol. 82, pp. 6927-6931, October, 1985.
	*Jahner, Detlev et al., « De novo methylation and expression of retroviral genomes during mouse embryogenesis, » Nature, vol. 298, pp. 623-628, August 12, 1982.
	*Joyner, Alexandra L. et al., « Production of a mutation in mouse En-2 gene by homologous recombination in embryonic stem cells, » Nature, vol. 338, pp. 153-156, March 9, 1989.
	*Kapp, Ursula et al., « Treatment of Non-Obese Diabetic (NOD)/Severe-Combined Immunodeficient Mice (SCID) with flt3 Ligand and Interleukin-7 Impairs the B-Lineage Commitment of Repopulating Cells after Transplantation of Human Hematopoietic Cells, » Blood, vol. 92, no. 6, pp. 2024-2031, September 15, 1998.
	*Keown, Wayne A. et al., « Methods for Introducing DNA into Mammalian Cells, » Methods in Enzymology, vol. 185, pp. 527-537, 1990.
	*Kim, Hyung-Suk et al., « Recombinant fragment assay for gene targeting based on the polymerase chain reaction, » Nucleic Acid Res., vol. 16, pp. 8887-8903, 1988.
	*Lapidot, Tsvee et al., « Immune-deficient SCID and NOD/SCID mice models as functional assays for studying normal and malignant human hematopoiesis, » J. Mol. Med., vol. 75, pp. 664-673, 1997.
	*Longo, Dan L. et al., « Early Appearance of Donor-Type Antigen-Presenting Cells in the Thymuses of 1200 R Radiation-Induced Bone Marrow Chimeras Correlates with Self-Recognition of Donor I Region Gene Products, » The Journal of Immunology, vol. 130, no. 6, June, 1983.
	*Longo, Dan L. et al., « Bone marrow-derived thymic antigen-presenting cells determine self-recognition of Ia-restricted T lymphocytes, » Proc. Natl. Acad. Sci., USA, vol. 82, pp. 5900-5904, September, 1985.
Examiner	Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. PTO-1449

## INFORMATION DISCLOSURE CITATION

Attorney Docket No.: GC589-4	Serial No.: 09/938,689
Applicant: Huang et al.	
Filing Date: August 23, 2001	Group: 1636
Page 4 of 6	Date of this Submission: April 15, 2003



## OTHER DOCUMENTS

Examiner's	
Initials	Author, Title, Date, Pertinent Pages, etc.
	*Longo, Dan L. et al., « T-cell specificity for H-2 and Ir gene phenotype correlates with the phenotype of thymic antigen-presenting cells, » Nature, vol. 287, pp. 44-46, September 4, 1980.
	*Mansour, Suzanne L. et al., « Disruption of the proto-oncogene int-2 in mouse embryo-derived stem cells : a general strategy for targeting mutations to non-selectable genes, » Nature, vol. 336, pp. 348-352, November 24, 1988.
	*Markle, ed., Methods in Molecular Biology, vol. 54, 1997.
	*Markowitz, Jay S. et al., « Class II-positive hematopoietic cells cannot mediate positive selection of CD4 <sup>+</sup> T lymphocytes in class II-deficient mice, » Proc. Natl. Acad. Sci., USA, vol. 90, pp. 2779-2783, April, 1993.
	*Mazurier et al., "A novel immunodeficient mouse model—RAG2 x common cytokine receptor gamma chain double mutants—requiring exogenous cytokine administration for human hematopoietic stem cell engraftment," J. of Interferon and Cytokine Research (1999) 19:533-541 (XP-000972854)
	*Mertsching, Elisabeth et al., « Phenotypic and functional analysis of B lymphopoiesis in interleukin-7-transgenic mice : expansion of pro-pre-B cell number and persistence of B lymphocyte development in lymph nodes and spleen. « Eurl. J. Immunol., vol. 26, pp. 28-33, 1996.
	*Molotkov, Andrei et al., « Tumor growth and food intake in interleukin-6 gene knock-out mice, » Cancer Letters, vol. 132, pp. 187-192, 1998.
	*Mombaerts et al., "RAG-1-deficient Mice have no mature B and T lymphocytes," Cell (1992) Vol. 68, pp. 869-877 (XP002081285)
	*Monaco, Anthony P. et al., « YACs, BACs, PACs and MACs : artificial chromosomes as research tools, » Trends Biotechnol., vol. 12, pp. 280-286, 1994.
	*Nandi, Asit K. et al., « Regulated expression of genes inserted at the human chromosomal $\beta$ -globin locus by homologous recombination, » Proc. Natl. Acad. Sci. USA, vol. 85, pp. 3845-3849, June, 1988.
	*Oka et al., "An interleukin-6 transgene expressed in B lymphocyte lineage cells overcomes the T cell-dependent establishment of normal levels of switched immunoglobulin isotypes," Database Chemabs 'Online! Chem. Abst. Serv. (1995) Eur. J. Immunol. 25(5), 1332-7 (XP-002157439)
	*Paul ed. Fundamental Immunology, 4th edition, Lippincott-Raven Press, 1999.
	*Pawlowski, Tomasz et al., « Positive selection of T lymphocytes on fibroblasts, » Nature, vol. 364, pp. 642-645, August 12, 1993.
	*Perry, Anthony et al., « Mammalian Transgenesis by Intracytoplasmic Sperm Injection, » Science, vol. 284, pp. 1180-1183, May 14, 1999.
	*Plumio, Françoise et al., « Phenotype and Function of Human Hematopoietic Cells Engrafting Immune-Deficient CB17-Severe Combined Immunodeficiency Mice and Nonobese Diabetic-Severe Combined Immunodeficiency Mice After Transplantation of Human Cord Blood Mononuclear Cells, » Blood, vol. 88, no. 10, pp. 3731-3740, November 15, 1996.
	*Ragoussis, Jiannis et al., « Mitotic recombination of yeast artificial chromosomes, » Nucleic Acids Research, vol. 20, no. 12, pp. 3135-3138, 1992.

Examiner	Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. PTO-1449

## INFORMATION DISCLOSURE CITATION

Attorney Docket No.: GC589-4	Serial No.: 09/936,689
Applicant: Huang et al.	
Filing Date: August 23, 2001	Group: 1636
Page <u>5</u> of <u>6</u>	Date of this Submission: April 15, 2003



## OTHER DOCUMENTS

Examiner's	
Initials	Author, Title, Date, Pertinent Pages, etc.
	*Ramirez, Manuel et al., « Mature human hematopoietic cells in donor bone marrow complicate interpretation of stem/progenitor cell assays in xenogeneic hematopoietic chimeras, » Experimental Hematology, vol. 26, pp. 322-344, 1998.
	*Ramsay, Michele, « Yeast Artificial Chromosome Cloning, » Molecular Biotechnology, vol. 1, pp. 181-201, 1994.
	*Rich, Benjamin E. et al., « Cutaneous Lymphoproliferation and Lymphomas in Interleukin 7 Transgenic Mice, » J. Exp. Med., vol. 177, pp. 305-316, February, 1993.
	**Sambrook et al., Molecular Cloning : A Laboratory Manual, 2nd ed., vols. 1-3, Cold Spring Harbor Laboratory, 1989.
	*Shepherd, Nancy S. et al., « The P1 Vector System for the Preparation and Screening of Genomic Libraries, » Genetic Engineering, vol. 16, pp. 213-227, 1994.
	*Shinkai et al., "Rag-2-deficient mice lack mature lymphocytes owing to inability to initiate V(D)J rearrangement," Cell (1992) Vol. 68, no. 5, pp. 855-867 (XP-000604771)
	*Stewart, Colin L. et al., « Expression of retroviral vectors in transgenic mice obtained by embryo infection, » The EMBO Journal, vol. 6, no. 2, pp. 383-388, 1987.
	*Struble, Robert G. et al., « Apolipoprotein E. Immunoreactivity in human and mouse olfactory bulb, » Neuroscience Letters, vol. 267, pp. 137-140, 1999.
	*Thomas, Kirk R. et al., « Site-Directed Mutagenesis by Gene Targeting in Mouse Embryo-Derived Stem Cells, » Cell, vol. 51, pp. 503-512, November 6, 1987.
	*Thompson, Simon et al. « Germ Line Transmission and Expression of a Corrected HPRT Gene Produced by Gene Targeting in Embryonic Stem Cells, » Cell, vol. 56, pp. 313-321, January 27, 1989.
	**Tijssen, Laboratory Techniques In Biochemistry and Molecular Biology—Hybridization with Nucleic Acid Probes, Elsevier, New York, 1993.
	**Tsuji et al. ed., HLA 1991, Oxford University Press, 1992.
	*Uehira, Masahiro et al., « Immunologic Abnormalities Exhibited in IL-7 Transgenic Mice with Dermatitis, » The Journal of Investigative Dermatology, » vol. 110, no. 5, pp.740-745, May 5, 1998.
	*Valenzona, Homer O. et al., « Prelymphomatous B cell hyperplasia in the bone marrow of interleukin-7 transgenic mice : Precursor B cell dynamics, microenvironmental organization and osteolysis, » Experimental Hematology, vol. 24, pp. 1521-1529, 1996.
Examiner	Date Considered
Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. PTO-1449	

RECEIVED  
APR 24 2003  
TECH CENTER 1600



